



Modified PTO/SB/33 (10-05)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number

Q83547

Mail Stop AF
Commissioner for Patents
P.O. Box 1450 Alexandria, VA 22313-1450

Application Number

10/507,105

Filed

September 10, 2004

First Named Inventor

Takayuki FUJI

Art Unit

1655

Examiner

Paul C. Martin

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal

The review is requested for the reasons(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

☒ I am an attorney or agent of record.

Registration number 26,577

Joseph J. Ruch, Jr.
Signature

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August 10, 2006
Date



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q83547

Takayuki FUJI

Appln. No.: 10/507,105

Group Art Unit: 1655

Confirmation No.: 2105

Examiner: Paul C. Martin

Filed: September 10, 2004

For: REAGENT FOR MEASURING ALANINE AMINOTRANSFERASE ACTIVITY

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to the new Pre-Appeal Brief Conference Pilot Program, and further to the Examiner's Final Office Action dated April 10, 2006, and the Advisory Action dated July 28, 2006, Applicant files this Pre-Appeal Brief Request for Review. This Request is also accompanied by the filing of a Notice of Appeal and a Petition for Extension of Time.

In the final Office Action of April 10, 2006, claims 12 - 15, 17 - 20 and 22 - 25 were rejected under 35 U.S.C. § 112, second paragraph, particularly relating to the use of the term "exhibiting" in claims 12 and 17 *vis-à-vis*, the use of the term "inhibiting" in claims dependent thereon. In the Advisory Action, based on the Examiner's comments at page 2, it is understood that Applicant's comments were persuasive and the issue has been obviated.

Applicant turns now to the remaining rejections at issue:

Rejections under 35 U.S.C. §102(b) or §103(a)

In the final Office Action, at pages 2 - 4, claims 11 - 13, 15 - 20 and 21 - 25 were rejected under 35 U.S.C. § 102(b) based on U.S. Patent 4,241,179 (Madappally et al); furthermore, at pages 4 - 6 of the final Office Action, claims 11 - 25 were rejected under 35 U.S.C. § 103 based on Madappally et al. In the Advisory Action, the Examiner indicated that rejections under 35 U.S.C. § 102(b) and 103(a) based on "Misapply" (understood to be intended to refer to Madappally et al) were maintained.

For the reasons of record and set forth below, Applicant respectfully submits that the rejections based on the Madappally et al reference are based on a defective interpretation of the teachings of the Madappally et al reference, and accordingly withdrawal of these rejections is respectfully requested.

Differences between the present invention and the method disclosed in Madappally et al

As described in the Remarks of the Amendment Under 37 C.F.R. §1.116 filed July 10, 2006 (see page 8, second and third paragraphs), the present invention is different from the method disclosed in the Madappally et al reference, particularly with respect to the reaction system for measuring alanine aminotransferase (ALT) activity. That is, the present invention is based on the reaction formulae (I) and (II), whereas the method disclosed in the Madappally et al reference is based on the reaction formulae (I) and (III).

To further illustrate this difference in an easily understandable manner, Applicant has prepared and encloses herewith **Appendix A**. In the present invention, on the basis of the

reaction formulae (I) and (II) (see reaction system A shown in **Appendix A**), the ALT activity is determined by "measuring a decreased amount of reduced nicotinamide adenine dinucleotide (NADH) or an increased amount of oxidized nicotinamide adenine dinucleotide (NAD)" (see claim 11), caused by the reaction of formula (II).

In contrast, in the method disclosed in the Madappally et al reference (see reaction system B in **Appendix A**), the ALT activity is determined by measuring a decreased amount of oxidized nicotinamide adenine dinucleotide (NAD) or an increased amount of reduced nicotinamide adenine dinucleotide (NADH), caused by the reaction of formula (III).

Further with respect to the reaction formula (II), in the method disclosed in the Madappally et al reference (reaction C in **Appendix A**), this reaction is carried out in order to avoid the effects of internal LD contained in biological fluids (see page 14, line 4 from the bottom to page 15, line 5 of the Amendment under 37 C.F.R. §1.111 filed January 30, 2006). That is, in Madappally this reaction is a mere pretreatment before measuring the ALT activity.

Conclusion

In conclusion, it is respectfully submitted that neither the rejection under 35 U.S.C. § 102(b) nor the rejection under 35 U.S.C. § 103(a), both of which are based on the Madappally et al reference, are sustainable, since different reaction sequences are involved in the presently claimed invention *vis-à-vis* the Madappally et al reference. Therefore, independent claim 11 and claims 12 - 25 dependent thereon are respectfully submitted to the novel, nonobvious, and patentable over the Madappally et al reference.

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Attorney Docket No.: Q83547

Accordingly, allowance of the pending claims 11 - 25 of the present application, or at least reopening of the prosecution on the merits, is respectfully requested.


Respectfully submitted,

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Appendix A

